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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,411	03/09/2004	Chih-Ming Chen	300.1005 CON	9033
7590 12/29/2005 DAVIDSON, DAVIDSON & KAPPEL, LLC 14th Floor 485 Seventh Avenue New York, NY 10018			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/796,411	Applicant(s) CHEN ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,25 and 28-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23,25 and 28-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 9/16/05

Double Patenting

1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

2. Claims 1-6, 9-20 and 28 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-21 of prior U.S. Patent No. 6,790,459. This is a double patenting rejection.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. The claims are drawn to a controlled release oral dosage form as described in Figures 1-3. However claims must stand alone and be fully described in and of themselves. Correction is required to overcome this rejection.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-20,25 and 28-30 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Whitcomb (USPN 6,011,049 hereafter '049) and Byrd et al (USPN 6,191,162 hereafter '162). The claims are drawn to controlled release formulation comprising metformin where the dosage forms comprises a core and membrane coating. The core and coating comprise common excipients well known in the art such as binders and plasticizers.

9. As discussed above the '049 patent discloses a metformin formulation comprising common excipients in tablet or capsule form, however the disclosure is silent to a specific core or coating structure. This is however well known in the art and would be obvious to one of ordinary skill. This can be seen in the '162 patent.

10. The '162 patent teaches a controlled release formulation capable of reducing serum glucose levels (abstract). The formulation comprises multiple pharmaceuticals including biguanides such as metformin (col. 8, lin. 23-61). The cores include excipients like binders and absorption enhancers such as polyvinylpyrrolidone and fatty acid esters (mono-, di-, and triglycerides (col. 18, lin. 30-37, lin. 55-60). The coating includes alkylcelluloses, and other common hydrophobic coatings such as cellulose acetate phthalate (col. 12, lin. 57-65). The

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coating can also be micro-porous allowing for small amounts of the drug to be released (col. 16, lin. 35-68). The coatings include plasticizers common in the art such as polyethylene glycol and propylene glycol (col. 19, lin. 27-42). The dosage forms include multi-, or single unit granules (col. 12, lin. 39-56). The formulation can be pressed in to min-tablets and filled into capsules (col. 17, lin. 9-32). These coatings and excipient would all have been obvious to the artisan of ordinary skill and would have motivated them to use the excipients in order to tailor the release of the active agent.

11. Regarding the mean serum concentration values, it is the position of the Examiner that these values do not impart patentability barring a showing of an unexpected result. The prior art presents controlled release oral dosage forms that reduce the serum glucose levels in human patients with NIDDM, comprising a dosage of metformin along with a control releasing membrane. The dosage form of Byrd comprises micro-pores that act as passageways for the drug to pass through. The combination of the drug of Whitcomb and the structure of Byrd would result in a formulation that lowered the serum glucose level in a patient with NIDDM. Burden is shifted to applicant to provide evidence of a patentable distinction in the form of an unexpected result regarding the mean plasma concentration.

12. With these things in mind it would have been obvious to one of ordinary skill in the art to combine the coatings and other excipients of the '162 patent with the formulation of the '042 in order to better control the release of the metformin. It would have been obvious to combine the teachings with an expected result of an improved controlled release formulation capable of treating diabetes mellitus and lowering the serum blood glucose levels in a patient in need thereof.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618


MP Young

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